POINT OF CARE
TESTING

CoaguChek® XS

User's Manual
Manuale per l'uso

Roche

On the packaging, on the type plate of the monitor and in the User's Manual you may encounter the following symbols and abbreviations shown here with their meaning:

Use by/Expiry date

LOT

Lot number

IVD

For in vitro diagnostic use

CE 0123

This product fulfills the requirement of Directive 98/79/EC on in vitro diagnostic medical devices.

REF

Catalogue number

Please consult instructions for use

Caution (refer to accompanying documents). Please refer to safety-related notes in the manual accompanying this instrument.

Manufacturer

Store at

The CoaguChek XS System

The CoaguChek XS System is used for quantitative monitoring of coagulation values (common terms: thromboplastin time, PT, Quick value) with CoaguChek XS PT test strips.

Self-monitoring and self-adjustment of oral coagulation therapy using coagulation values determined with the aid of the CoaguChek XS System may only be undertaken after consultation with your doctor and comprehensive instruction by a qualified healthcare professional. Your pharmacist / specialist supplier can provide you the training and/or put you in touch with associations or institutions offering training in coagulation self-monitoring. Please read the special notes on INR self-monitoring in the package insert accompanying the test strips.

The CoaguChek Softclix lancing device is intended only for patient self-monitoring by a single person. **It must not be used to collect blood in a multi-patient setting as it does not incorporate any features to guard against cross-infection**.

Please note: This manual contains all the information you need to operate and care for the CoaguChek XS System. Please **read this entire manual carefully** before you use the monitor.

Last update user information: 2008-03

The CoaguChek XS System 3

Introduction 9
- The CoaguChek XS System 9
- Test principle 10
- Contents of the pack 10
- Operating conditions 11
- Quality control 12

About this manual 13
- Manual format 13

The CoaguChek XS monitor 16
- The CoaguChek XS monitor 17
- Batteries 18

Starting up 19
- Inserting the batteries 20

Code chip 23
- Inserting the code chip 24

Monitor setup 26
- Settings summary 27
- Setting up the monitor (Set Mode) 28
- Setting the date format 31
- Setting the date 32
- Setting the time format 34
- Setting the time 35
- Selecting the unit 36
- Setting the beep tone 37
- Setting the therapeutic range (INR) 38

Testing a capillary blood sample 43
Important notes 44
Getting a good capillary blood sample 46
Preparing to test 47
Performing a test 48
Notes concerning the results display 59
Testing by healthcare professionals 62
Getting a good capillary blood sample in a healthcare setting 63
Disposal by healthcare professionals 63

Memory 65
Viewing test results 65
Erasing memory 68

Cleaning 71
Cleaning the housing 71
Cleaning the test strip guide 72
Cleaning by healthcare professionals 74

Error messages 75
Error messages overview 76
Error messages after turning the monitor on 78
Error messages when preparing to test 80
Error messages after the code number was confirmed 84
Error messages during or after blood application 86
Error message during infrared downloads 92

Display information and symbols 94

Further information 97
Ordering 97
Product limitations 97

Product specifications 98
Operating conditions and technical data 98
Sample material 99
Storage and transport conditions 99
Disposal of the CoaguChek XS monitor 99
Information service 100
Repairs 100

Guarantee 101

Alphabetical index 102

Introduction

The CoaguChek XS System

The CoaguChek XS System (CoaguChek XS monitor and CoaguChek XS PT test strips) quantitatively determines prothrombin time (PT/Quick value/INR) using capillary blood from a fingertip or untreated venous whole blood. The CoaguChek XS System makes coagulation testing easy. The CoaguChek XS monitor guides you through the test step by step using the symbols in the display. The code chip accompanying the test strips contains lot-specific information about these test strips, including calibration data that allow the correct results to be calculated, and the expiry date for the test strips. You only need to insert the code chip, turn the monitor on, insert the test strip, and apply a blood sample. When the CoaguChek XS monitor is ready for a measurement, the result will be displayed about 1 minute after application of the sample. After the measurement, the monitor automatically stores the result in memory.

If you have any questions about the CoaguChek XS monitor, please contact your local customer support and service centre. You will find contact details on page 100.

Please note: Before you use the monitor for the first time (i.e. after you have first inserted the batteries), you must set the date and time correctly to allow you to carry out measurements properly. Each time you replace the batteries you need to check (and, if necessary adjust) the date and time.

Test principle

The CoaguChek XS PT test strip contains a lyophilized reagent (reagent in dried form). The reactive components of this reagent consist of thromboplastin and a peptide substrate. When a sample is applied, thromboplastin activates coagulation, which leads to the formation of thrombin. At the same time the monitor starts to measure the time. The enzyme thrombin cleaves the peptide substrate, generating an electrochemical signal. Depending on the time elapsed when it first appears, this signal is then converted by means of an algorithm into customary coagulation units (INR, %Quick, seconds) and the result is displayed.

Contents of the pack

- CoaguChek XS monitor
- 4 alkali-manganese batteries, 1.5 V, type AAA
- CoaguChek Softclix lancing device with instructions for use
- CoaguChek Softclix Lancet
- System carry-case
- User's Manual

Operating conditions

To ensure that your CoaguChek XS System functions properly, please observe the following guidelines:

- Only use the monitor at a room temperature between 18°C and 32°C.
- Only use the monitor at a relative humidity between 10% and 85%.
- When testing, place the monitor on a level, vibration-free surface or hold it so it is roughly horizontal.
- If the monitor is to remain unused for a longer period of time, keep it in the carry-case supplied.
- Use the monitor only up to a maximum altitude of 4300 metres.

Electromagnetic interference

Strong electromagnetic fields may interfere with the proper operation of the monitor. Do not use the monitor near strong electromagnetic fields.

Quality control

The CoaguChek XS System has a number of inbuilt quality-control functions such as:

- A check of the electronic components and functions every time the monitor is turned on.
- A check of the test strip temperature while a test is in progress.
- A check of the expiry date and lot information on the test strip.
- A quality control function is incorporated into the test strip. Quality control and system checks using control test solutions that you may be familiar with from other systems are no longer required.

About this manual

Manual format

The layout of this User's Manual has been specially designed to help you locate the most important information quickly and easily. Where illustrations are used, they always appear on the left side of the page with the accompanying explanation text on the right.

All instructions that require you to actively do something as well as especially important information appear on a blue background.

This symbol draws attention to the possible risk of sustaining injury or of damaging your health.

Example:

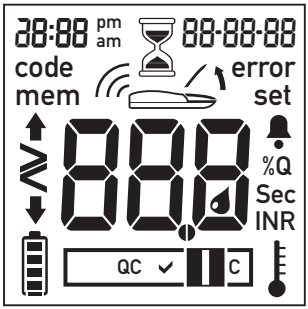
This column contains an illustration.

This column states what you should do at this point.

1 Press the **On/Off** button.

Example:

This column contains an illustration of the display screen.



This column contains information linked to the display screen.

Each time you turn on the monitor, it runs a full display check, briefly showing all the symbols that might be displayed.

To prevent reading errors, check regularly that all segments of the symbols are showing.

The CoaguChek XS monitor

The CoaguChek XS monitor

A Display
Shows results, information, symbols and results recalled from memory.

B M (memory) button
Press this button to recall results from memory and to change the monitor settings. You also press this button to confirm the code number displayed before each test.

C On/Off button
Press this button to turn the monitor on or off.

D Measurement chamber cover
Remove this cover to clean the test strip guide.

E Test strip guide
Insert the test strip here.

F Battery compartment cover
Covers the battery compartment (4 1.5 V alkali-manganese batteries type AAA).

G Code chip slot
Insert the code chip here.

H Set button
Press this button to enter or change the monitor settings.

I Infrared window
You can transfer data stored in memory via this infrared interface.

Batteries

To save power, the CoaguChek XS monitor automatically turns itself off after 3 minutes unless a button has been pressed or a new test strip has been inserted. When the monitor turns itself off, all results obtained up to that point remain in memory. The monitor briefly indicates the battery power level when it is turned on. The battery symbol is divided into four segments which correspond to the battery power level.

When replacing the batteries you must insert the new batteries within one minute of removing the old ones, to keep the date and time settings. If you take longer than this, you must re-enter the date and time. Use only alkali-manganese batteries type AAA.

The CoaguChek XS monitor is shipped with high quality batteries. Since quality varies among different battery brands, Roche recommends replacing your used batteries with new batteries of a similar high quality and not mixing different brands. Do not mix new and already used batteries.

Please be aware that battery life may be affected by many factors, such as battery quality, operating conditions (e.g. ambient temperature), frequency of use, and test duration.

Results are retained in memory together with the date and time even when no batteries are inserted. All other settings are retained, too.

Think of the environment. Dispose of used batteries sensibly.

Do not throw batteries onto a fire. They may explode!

Starting up

Before using the monitor for the first time, carry out the following steps:

1 Insert the batteries

2 Insert the code chip (you can also carry out this step immediately before testing)

3 Set the current date and time

4 Select the coagulation unit in which the results are to be displayed

Inserting the batteries

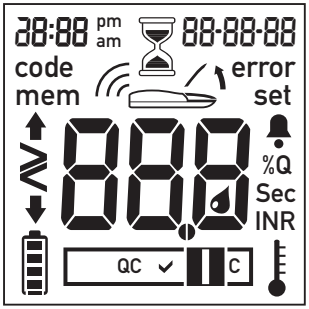
1 With the monitor turned off, turn it over.

2 Gently press the tab on the battery compartment cover towards the centre of the monitor and lift off the cover.

3 Insert the four batteries in the battery compartment as indicated. Pay attention to the positions of "+" (top of battery) and "-" (flat end). Once you have inserted the batteries, the monitor turns itself on after about 5 seconds.

Only use alkaline manganese batteries (1.5 V, AAA). Think of the environment. Dispose of used batteries sensibly.

4 Close the battery compartment.

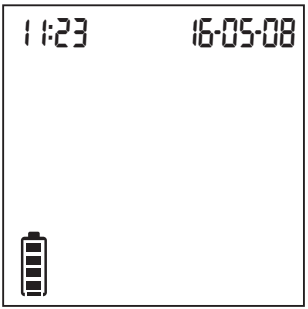


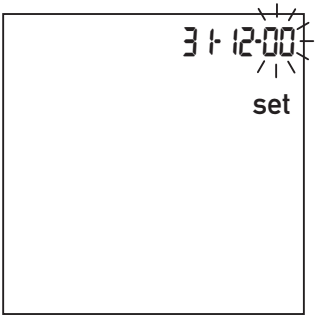
5 Check that all of the display symbols are displayed properly. Results may be misread if a segment is missing.

Tip

If the display check when you turn on the monitor is too quick, you can put it “on hold” by pressing and holding down the On/Off button ⏻ the next time you turn the monitor on.

For as long as you keep the button pressed, the display remains frozen.





6 On the next screen that appears check that the date and time are correctly set.

If these have not yet been set or if they have been lost (because the batteries were removed from the monitor for more than one minute), your CoaguChek XS monitor now automatically enters Set Mode. After you have set the date and time, the monitor enters Test Mode. If you wish to enter any further settings, turn to the chapter *Setting up the monitor (Set Mode)* starting on page 28.

7 Turn the monitor off again when the settings are correctly entered.

Code chip

The code chip provides the monitor with important information which it needs to perform the coagulation test. The chip contains information about the test method, the lot number and the expiry date. The monitor is ready to use once the code chip has been inserted.

- Each time you test, check that the correct code chip is inserted in the monitor.
- When you start each new pack of test strips you must remember to remove the old code chip from the monitor and replace it with the new code chip supplied with the test strips.
- Each code chip belongs to a particular lot of test strips. Only remove the code chip when you are testing with test strips taken from a new pack (with a new code chip).
- Protect the code chip from moisture and equipment which produces magnetic fields.

Inserting the code chip

1 Remove the old code chip, if one is inserted in the monitor.

Discard the old code chip with your household waste.

2 Always make sure that the number on the code chip matches the number on the label of the test strip container.

Using the wrong code chip can produce incorrect results.

3 Slide the new code chip into the slot on the side of the monitor as shown until you feel it snap into place.

Every time you insert a test strip in the monitor, the display shows the number of the code chip that is presently inserted. Always compare the code number you see on the display with the number that is printed on the test strip container. If the two numbers are identical, confirm by pressing the **M** button (see page 51).

If the code numbers are not identical, turn the monitor off and insert the correct code chip. Discard the old code chip to prevent mix-ups.

If the code chip is missing or incorrectly inserted, **Error** and **Code** appear in the display (please refer also to the chapter *Error messages* starting on page 75).

Monitor setup

Please note: If you have **not** set the date (after turning on for the first time or because the batteries were removed from the monitor for more than one minute), you cannot perform a test. In that case turning on the monitor takes you immediately to Set Mode, where you must set the date and time. Once you have set date and time the monitor automatically enters Test Mode.

Settings summary

Setting	Options	Presetting *
Date format	Day-Month-Year (31-12-00) Month-Day-Year (12-31-00) Year-Month-Day (00-12-31)	31-12-00
Date		31-12-00
Time format	24-hour format (24h) 12-hour format (12h) with a.m./p.m.	24h
Time		12:00
Unit	%Q Sec INR	INR
Beep tone	On Off	On
Therapeutic range (only INR)	On Off	Off
Set range [INR]	Lower range (1.5 – 3.5) Upper range (2.5 – 4.5)	1.5 INR 2.5 INR

* “Presetting” means the setting that is in the monitor when it leaves the factory.

Setting up the monitor (Set Mode)

All settings are entered with the **Set** button and the **M** button.

1 If the monitor did not automatically enter Set Mode when you turned it on, press the **Set** button (on the left side of the monitor) to put it in Set Mode.

You can also press the **Set** button to change to Set Mode when the monitor is already turned on.

2 If the currently displayed setting is correct (e.g. the date is correct and you only wish to change the time), you can press the **Set** button to move on to the next setting,
or

3 Press the **M** button to change the setting that is currently flashing. You may press the **M** button repeatedly (or press it and hold it down) until you have reached the correct setting. Settings where there are only two options (time format, beep tone) can be toggled on and off with the **M** button.

4 Press the **Set** button again to confirm the current setting (which is saved to memory) and move on to the next one.

5 You can only move forward from one setting to the next, not backward. Corrections can only be made by repeating the settings. You can exit the settings procedure at any time by pressing the On/Off button ⏻. All settings you have already entered are retained.

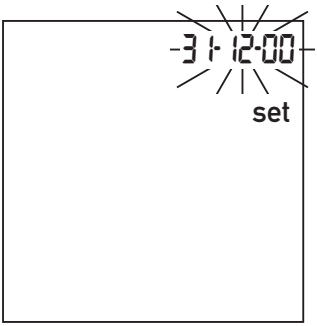
Setting the date format

First, select the date format (**the entire date display flashes**). The display options are as follows:

- **31-12-00 (= presetting) Day-Month-Year**
- 12-31-00 Month-Day-Year
- 00-12-31 Year-Month-Day

When elements in the display are surrounded by a halo, it indicates that they are flashing in the monitor's display.

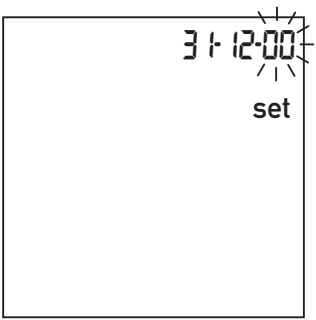
Pressing the **Set** button takes you to Set Mode. This is indicated by the word "**set**" in the display.

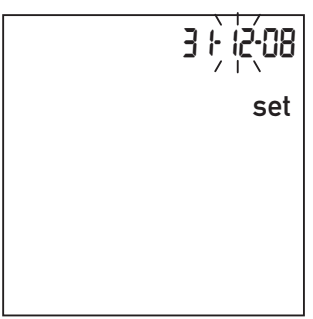


1. Press the **M** button to select the date format. 31-12-00 flashes in the display. You can now select the date format.
2. Press the **Set** button to save this setting and continue with the date setting. The display automatically moves on to the date setting.

Setting the date

The next three settings involve entering first the **year**, then the **month**, and finally the **day**.



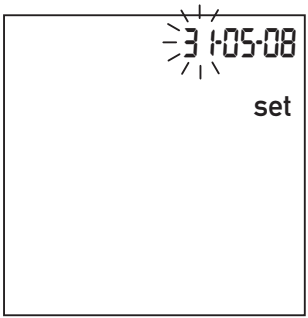


3 Press the **M** button to change the number that is currently flashing and set the current year.

4 Press the **Set** button to save the year. The display then automatically moves on to the month setting.

5 The preset month flashes. Press the **M** button until the correct month is displayed.

6 Press the **Set** button to save the setting. The display then automatically moves on to the day setting.

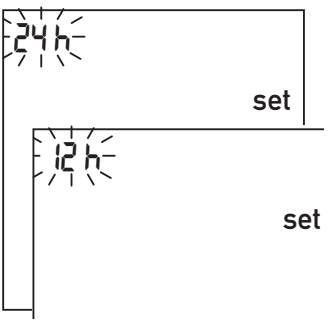


7 The preset day flashes. Press the **M** button until the correct day is displayed.

8 Press the **Set** button to save the setting. The display then automatically moves on to the time format setting.

Setting the time format

Now select the time format. You can choose between the 24-hour time format (presetting) and the 12-hour time format with “a.m.” or “p.m.”.

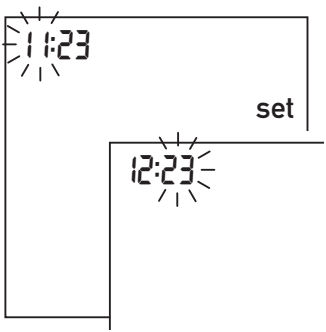


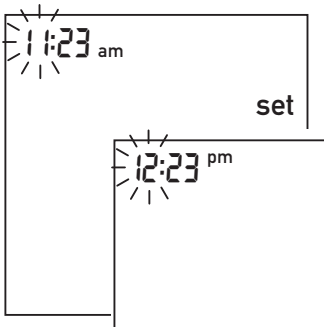
9 Press the **M** button to toggle between 24-hour and 12-hour format.

10 Press the **Set** button to save the correct setting and continue with the time setting. The display automatically moves on to the time setting.

Setting the time

First you set the hour, then the minutes.





11 Press the **M** button to change the number that is currently flashing. Press the **Set** button to confirm. You can now set the minutes (again using the **M** button).

If you have selected the **12-hour** time format, "**a.m.**" changes to "**p.m.**" and vice versa when you reach "12:xx".

12 Press the **Set** button to save this setting and continue with selection of the unit for reporting the result.

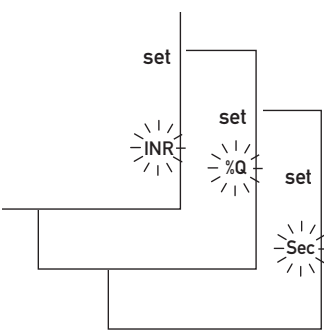
Selecting the unit

Choose the coagulation unit you wish the monitor to use to display the result. The options are:

- %Q
- Sec
- **INR (presetting)**

Ask your doctor if you are not sure which unit to select.

The current coagulation unit flashes.



13 Press the **M** button to cycle through the three options.

14 Press the **Set** button to save the correct unit. The display then automatically moves on to the beep tone setting.

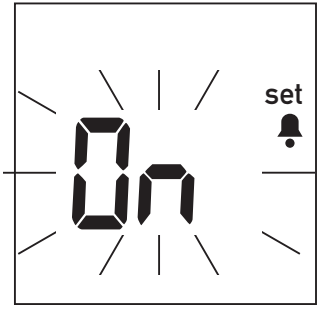
If you have selected “INR” as your coagulation unit, you have the option of entering your therapeutic target range. If you enter this, you will be able to see after every test whether the result is within your therapeutic target range (see page 38).

Setting the beep tone

After you have set the unit, you can choose whether you want the beep tone “On” or “OFF”. If you have selected “On,” the monitor will beep in the following situations:

- when it detects a test strip,
- when pre-heating of the test strip is complete and you need to apply a sample,
- when it detects a sample,
- when the result is displayed and
- if an error occurs (three short beeps).

We recommend you leave the beep tone turned on.



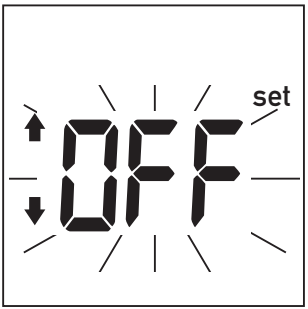
15 Press the **M** button to toggle between “OFF” and “**On**” (“On” is the presetting).

16 Press the **Set** button to save the chosen setting. The display automatically moves on to the next setting option.

Setting the therapeutic range (INR)

What happens next depends on the coagulation unit you have chosen for your results. If you selected “%Q” or “Sec”, the settings are now complete, and “End” appears in the display (see page 40).

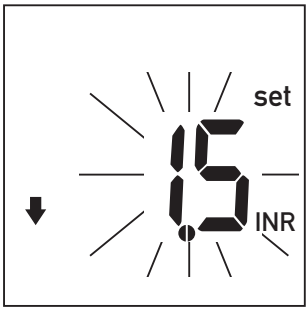
If you selected “INR” as the unit, you can now choose whether you want a further element to be displayed if the result is outside (above or below) your therapeutic target range. If you switch on this display option, an up or down arrow is displayed whenever the result is above or below the target range you have set. This highlights the fact that the result is outside your target range.

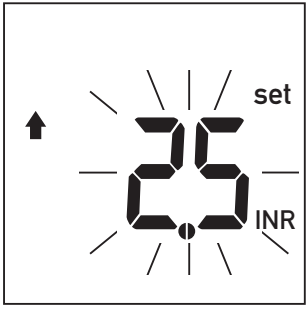


17 Press the **M** button to toggle between “**OFF**” and “On”.

18 Press the **Set** button to save the chosen setting and continue with the monitor setup.

If you have activated this display option (“On”), you are now able to enter the limits of your target range. Consult your doctor about what target range is appropriate for you.





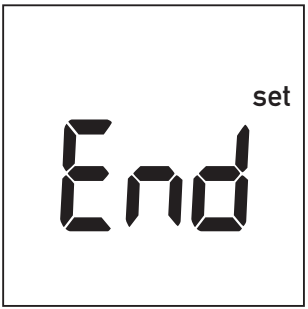
19 Press the **M** button to set the **lower** limit (symbolized by the down arrow) within the range 1.5 – 3.5 INR.

20 Press the **Set** button to save the chosen lower limit and continue with the upper limit setting.

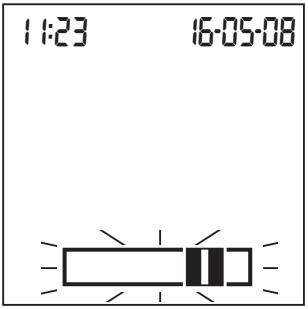
21 Now press the **M** button to set the **upper** limit (symbolized by the up arrow) within the range 2.5 – 4.5 INR. The selectable range will be at least 0.1 INR above the lower limit you have selected.

22 Press the **Set** button to save the chosen upper limit and close the monitor setup.

The monitor setup is now complete.



This display screen appears automatically after you have completed the last setting and remains for a few seconds to indicate that the setup procedure is now complete.



After that the monitor automatically enters Test Mode.

If you do not wish to perform a test at this point, turn the monitor off.

You can exit the monitor setup procedure at any time (e.g. if you have made an incorrect entry) by pressing the On/Off button ⏻. Then enter the monitor setup again by turning on the monitor with the **Set** button, and press the **Set** button repeatedly until you reach the setting you wish to change.

Testing a capillary blood sample

What you need

- CoaguChek XS monitor
- The code chip already inserted in the monitor (each test strip container has its own code chip)
- Test strips belonging to the code chip mentioned above
- Lancing device (e.g. CoaguChek Softclix)
- Lancet (e.g. CoaguChek Softclix Lancet)
- Lint-free swab or paper tissue

Important notes

Always …

- … close the container immediately after having removed a test strip.
- … operate the monitor at an ambient temperature between 18°C and 32°C.
- … place the monitor on a level, stable surface (table) or hold it so it is roughly horizontal.
- … follow the information on correct handling of test strips in the package insert.
- … keep the test strip guide and housing clean. See also the chapter entitled *Cleaning* (page 71).

Never …

- … store the monitor at extreme temperatures.
- … store the monitor in damp or humid conditions without protection.
- … remove or insert the code chip while the monitor is performing a test.
- … use the code chip from a pack other than the one in use.
- … touch or remove the test strip during a test.
- … wait more than 15 seconds after lancing the fingertip before applying the blood.
- … add more blood after the test has begun.
- … perform a test with a drop of blood from a previous puncture.

Failure to comply with the above may lead to inaccurate results.

Getting a good capillary blood sample

To get a suitable drop of blood:

- Wash your hands in warm water and dry thoroughly.

Residues of water on the skin can dilute the drop of blood and so produce false results.

- Let your hand hang at your side before lancing your finger.
- Immediately after lancing, massage gently along the side of your finger to obtain a sufficiently large blood drop without pressing or squeezing too hard.

The CoaguChek Softclix lancing device is intended only for patient self-monitoring by a single person. **It must not be used to collect blood in a multi-patient setting as it does not incorporate any features to guard against cross-infection**.

Preparing to test

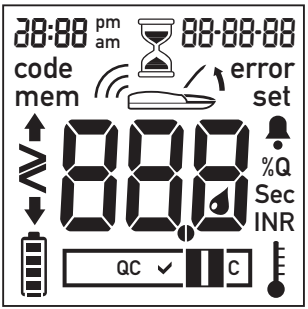
1 Have the test strip container to hand.

2 Make sure that the code chip belonging to these test strips is inserted in the monitor.

3 Prepare the lancing device by inserting a fresh lancet.

Do not lance your finger until asked to do so further on in this description.

Performing a test

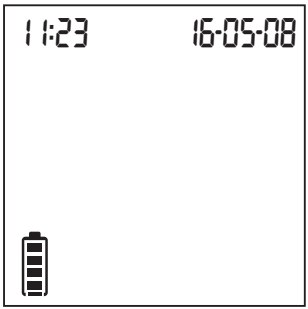


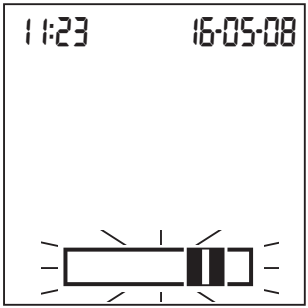
1 Wash your hands with soap and warm water. Dry them thoroughly.

Residues of water on the skin can dilute the drop of blood and so produce false results.

2 Place the monitor on a level, vibration-free surface or **hold it in your hand so it is roughly horizontal**. Turn the monitor on by pressing the On/Off button ⏻. Alternatively, you can insert a test strip to turn it on.

3 Check that all of the display symbols are displayed properly as shown on the picture. Results may be misread if a segment is missing.



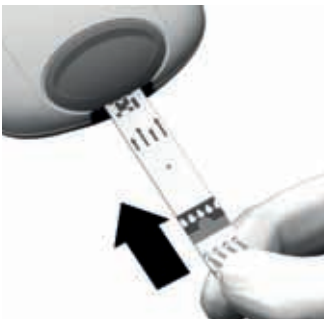


4 Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests.

5 Check that the date and time are correct. Correct any wrong entries as described from page 28 onwards.

6 The flashing test strip symbol prompts you to insert a test strip. Remove a test strip from its container. **Immediately after removing a test strip, close the container again with the stopper.**

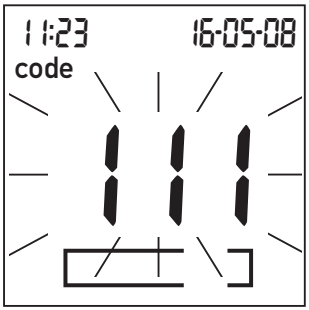
Exposure to external influences (e.g. humidity) may deteriorate the test strips and may lead to error messages.



7 Hold the test strip so the lettering “CoaguChek XS PT” is facing upward.

8 Slide the test strip into the test strip guide in the direction indicated by the arrows.

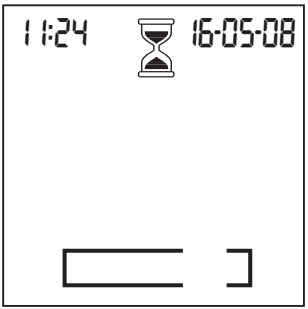
Slide the test strip in as far as it will go. A beep tone indicates that the monitor has detected the test strip (provided the beep tone is turned on in the settings).



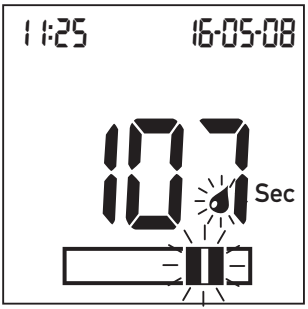
The code number of the code chip inserted in the monitor flashes in the display. Make sure that this number is identical with the code number printed on the test strip container.

9 If the two numbers are identical, confirm by pressing the **M** button.
The code number stops flashing.
If the code numbers are not identical, remove the wrong code chip and insert the code chip that was supplied with the test strips you are using.

Using the wrong code chip can produce inaccurate results.



The hourglass symbol shows that the test strip is warming up. When the warming-up process is complete, a further beep tone (provided the beep tone is turned on) indicates that you can now apply blood.



The blood drop symbol and the application area flash to indicate that the monitor is ready to perform the test and is waiting for blood to be applied.

At the same time a 120-second countdown begins. You must apply the drop of blood to the test strip within this time, otherwise you will receive an error message (**error,** and "**000**" where the result would normally be displayed).

10 Now lance the side of a fingertip with the lancing device.

We recommend obtaining the capillary blood from the side of the fingertip as this causes least pain.

Massage the lanced finger until a drop of blood is formed. **Do not press or squeeze the finger.**

Apply the first drop of blood from the finger.

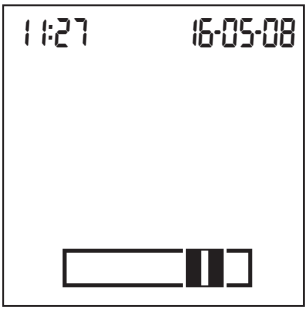
The CoaguChek Softclix lancing device is intended only for patient self-monitoring by a single person. **It must not be used to collect blood in a multi-patient setting as it does not incorporate any features to guard against cross-infection**.

11 Apply the blood directly from the finger to the semicircular, transparent sample application area of the test strip.

Alternatively, you can touch the blood drop against the side of the sample application area (instead of applying it to the centre from above). The test strip draws up the blood by capillary action.

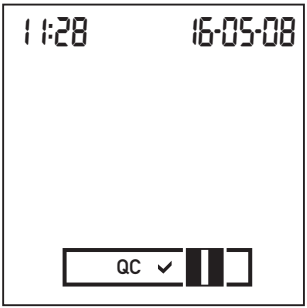
During this process you must hold the blood drop to the test strip until the flashing blood drop symbol has disappeared and the monitor beeps (provided the beep tone is turned on).

Apply the blood drop to the test strip **within 15 seconds** of lancing the fingertip. Applying blood after this period of time would falsify the result, as the coagulation process would already have begun.



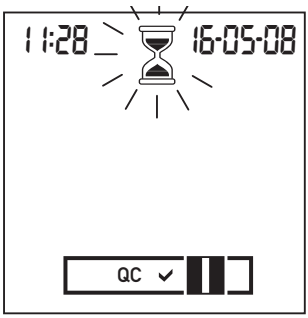
You hear a beep tone when you have applied enough blood (provided the beep tone is turned on). The blood drop symbol disappears and the test starts.

Do not add more blood. Do not touch the test strip until the result is displayed.



The monitor now performs an automatic quality control check on the test strip. “QC” appears in the display.

Following a successful outcome of the quality control check, a tick appears after “QC”.



It is at this point that the coagulation measurement begins. The hourglass flashes until the monitor has the result.

The result is displayed in the unit you chose when setting up the monitor. It is automatically saved to memory. You can change the unit if you wish by pressing the **Set** button while the result is displayed (see page 60).

Enter the test result in your patient logbook. When interpreting your result, please also read the test strip package insert carefully.

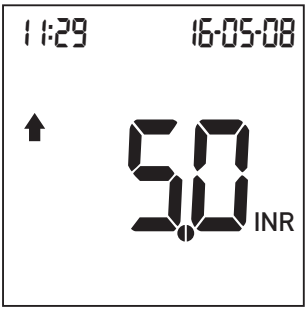
12 Remove the test strip from the measurement chamber.

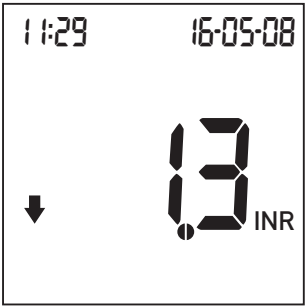
13 Turn the monitor off.

14 Discard the used lancet and test strip with your regular household waste.

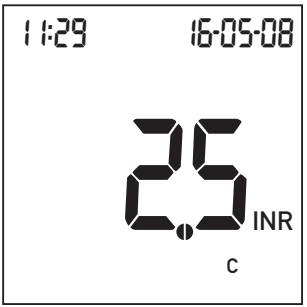
15 Clean the monitor if this becomes necessary (see page 71).

Notes concerning the results display





If your results are displayed in INR and you have activated the relevant option, values that are outside a defined target range are flagged with an up arrow (too high) or a down arrow (too low).



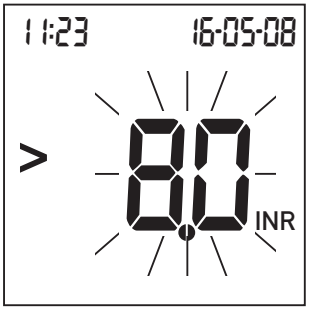
A “c” is displayed along with the result.

This may occur if the haematocrit value is very low or due to erroneous blood collection (e.g. wet hands). Repeat the measurement and make sure that your hands are dry. If the message persists, please contact your healthcare professional for a haematocrit check.

You can temporarily change the unit in which the result is presented by pressing the **Set** button while the result is displayed.

Each press of the button takes you to the next available unit (%Q - Sec - INR - …).

When you next perform a test, the result is again displayed in the standard unit you selected during setup.



The valid measuring ranges for CoaguChek XS PT test strips are:

- INR: 0.8–8.0
- %Q: 120–5
- Sec: 9.6–96

Results that are outside the measuring range are indicated by the symbols > (greater than) or < (smaller than) and flashing. In this case, refer to the section *Test limitations and known interferences* in the package insert supplied with the test strips, and repeat the test.

Testing by healthcare professionals

Follow the appropriate infection control guidelines in force in your facility.

- Wear protective gloves.
- Wash or disinfect the patient's finger and allow it to dry thoroughly.

Residues of water or disinfectant on the skin can dilute the drop of blood and so produce false results.

- Use only a lancing device that is approved for use by healthcare professionals (for example, the Safe-T-Pro Plus lancing device from Roche shown below). Follow the manufacturer's instructions for use in a multi-patient setting.

- Follow all health and safety regulations in force locally.

There is a potential risk of infection. Healthcare professionals using the CoaguChek XS monitor to perform tests in more than one patient must be aware that any object coming into contact with human blood is a potential source of infection. Healthcare professionals must also be aware that any cross-contamination is a potential source of infection for patients. (See: Clinical and Laboratory Standards Institute: Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition; CLSI document M29-A3, 2005).

Getting a good capillary blood sample in a healthcare setting

- Select and lance a puncture site along the side of a fingertip.
- Use gentle pressure, massage the finger towards the fingertip to encourage a drop of blood to form (approx. 10 µL).
- Follow the procedure for testing as outlined from page 47. Use only a lancing device that is approved for use by healthcare professionals (for example, the Safe-T-Pro Plus lancing device from Roche).

Disposal by healthcare professionals

Dispose of used items in line with the disposal policy of your hospital, institute or medical practice.

Memory

The CoaguChek XS monitor has a 100-value memory for saving results together with time and date.

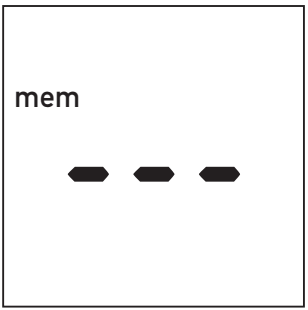
Viewing test results

1. Place the monitor on a level, vibration-free surface or hold it in your hand so it is roughly horizontal.
2. Press the **M** button to turn the monitor on in Memory Mode.

The monitor runs the usual display check and displays the most recent result. The display also shows **mem**, signifying that this is a result from memory and not one that has just been obtained by testing.

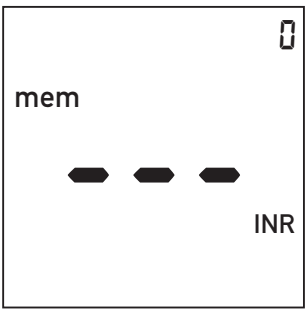
The date and time of testing are also shown.

3 Press the **M** button again to move one result back in time.



When you have reached the oldest result, the monitor displays a blank entry.

When all memory locations are full, the oldest result is erased to make way for the most recent one.



If no result has yet been saved, the display looks similar, but has a “0” in the top right corner.

You can temporarily change the unit in which the result is displayed (in the same way as directly following a test) by pressing the **Set** button while viewing a result in memory. Each press of the button takes you to the next available unit (see page 60).

Results can be downloaded from memory via an inbuilt infrared interface.

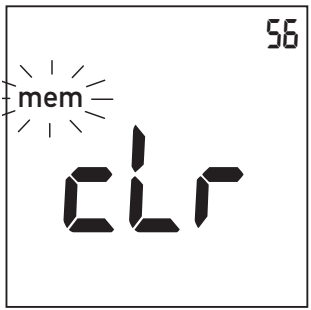
Please note: When downloading results via the infrared interface, avoid strong stray light, as this can cause the download to break off (see page 92).

For more information on downloading results to a suitable system (such as a PC), please call your local customer support and service centre (see page 100).

Erasing memory

You can erase the entire memory from your CoaguChek XS monitor. You cannot, however, erase individual results.

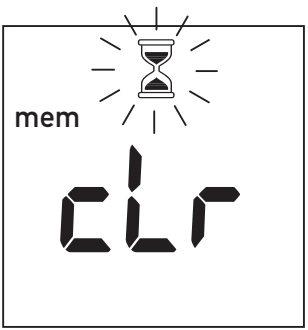
1. Place the monitor (which must be turned off) on a level, vibration-free surface or hold it so it is roughly horizontal.
2. To turn the monitor on,
   - first press **and hold down** the **M** button,
   - then press the **On/Off** button as well, and
   - hold down both buttons for at least 5 seconds.



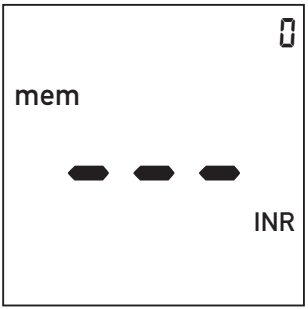
The monitor runs the usual display check and then displays **mem** (flashing) and **clr**. The number of results in memory is shown in the top right corner of the display.

3 Press the **M** button to confirm that you wish to erase the entire memory.

To exit Erase Mode without erasing the results, press the **On/Off** button instead.



The hourglass flashes while the results are being erased.



The counter is set to “0” and three bars are displayed, indicating that there are no results saved in memory (the entire memory has been erased).

Cleaning

Cleaning the housing

Clean the monitor whenever it becomes dirty. Turn off the monitor before cleaning it.

Use only the following items for cleaning:

- Ordinary lint-free swabs (available at pharmacies)
- Warm water with or without washing-up liquid
- Soft lint-free moistened cloth or cotton bud

Do **not** use sprays of any sort, as these may enter the monitor and damage it.

1. Clean the outside of the monitor with a lightly moistened cloth.
2. Then dry the monitor with a fresh cloth.

Cleaning the test strip guide

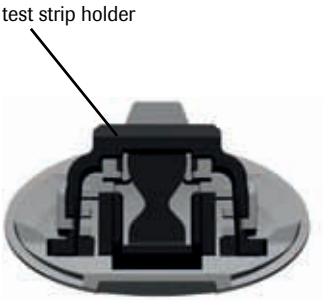
Check the test strip guide regularly for signs of soiling. If the test strip guide has become soiled with blood or any other material, you must clean this area.

1 Remove the measurement chamber cover by pressing upwards from the front (e.g. using your thumb-nail). You can rinse the detached measurement chamber cover (separately from the monitor) with water.

2 Clean the easily accessible white areas with a lint-free swab or a moistened cotton bud.

Make sure that **no** liquid enters the monitor. Do not insert any objects in the test strip guide. Doing so may damage the electrical contacts behind the test strip guide.

On completion of cleaning:



3 Let the inside of the test strip guide **dry for about 10 minutes.**

4 After this time, re-attach the measurement chamber cover to the housing, ensuring that the test strip holder is in the correct position and properly attached.

5 Make sure that the cover is properly closed. You will hear it snap into place.

Cleaning by healthcare professionals

Use 70% ethanol or isopropyl alcohol to clean the monitor. We recommend a mixture of 1-propanol, 2-propanol and glutaraldehyde, sold in some countries under the brand name “Bacillol plus”.

- Make sure the meter is off
- Gently wipe the meter’s surface.
- Cotton buds, wipes and cloths lightly moistened with disinfectant are all suitable for cleaning the meter.
- Allow areas you have wiped time to dry thoroughly.
- Remove any fluff or lint that may remain.

Refer to the section “Cleaning” (page 71) for further information.

Observe the following precautions to avoid damaging the system:

- Make sure that no liquid enters the meter.
- Do not spray anything onto the meter and do not immerse it in liquid. Doing so may damage the meter’s internal components and stop it from working properly.

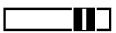
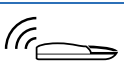
- Observe the disinfection guidelines of your institution.

Error messages

Depending on the circumstances an error message may appear on the display of your monitor. Your first step on receiving an error message should be to try the solution suggested for that error. If the problem persists, please contact your local customer support and service centre (see page 100).

A complete list of display messages and symbols is provided in this User's Manual starting on page 94.

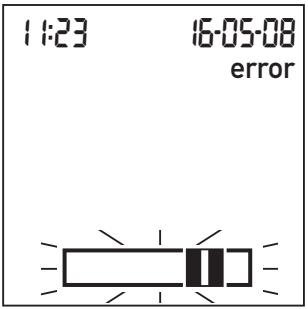
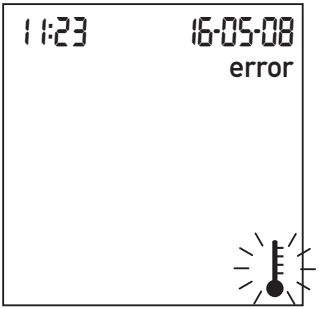
Error messages overview

Error message (always prefaced by **error**)	Brief description	Refer to page
Test strip symbol flashing 	Test strip in monitor or	78
	test strip unusable or the test strip is not a CoaguChek XS PT test strip	82
Temperature symbol flashing	Monitor too warm or too cold	78
Battery symbol flashing	Battery level too low	80
Cover symbol flashing	Measurement chamber cover open	80
IR symbol flashing 	Infrared download error	92
QC symbol flashing QC	Quality control: test strip unusable	88
Code symbol flashing code	Code chip error	82

Error message (always prefaced by **error**)	Brief description	Refer to page
Error number: 000	Allowed time for blood application exceeded	86
Error number: 3	Beyond expiry date	84
Error number: 4	Test strip unusable	84
Error number: 5	Blood application error	86
Error number: 6	Measurement error	88
Error number: 7	Measurement error	90
Error number: 8	Diagnostic testing error	92

Error numbers 1 and 2 are reserved for internal purposes by Roche.

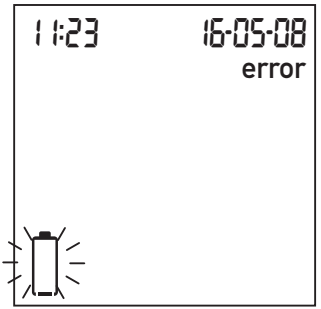
Error messages after turning the monitor on

Display	Description of error
	**Error: test strip** A test strip was already inserted when the monitor was turned on with the **On/Off** button.
	**Error: ambient temperature** The monitor is too cold or too warm to measure correctly.

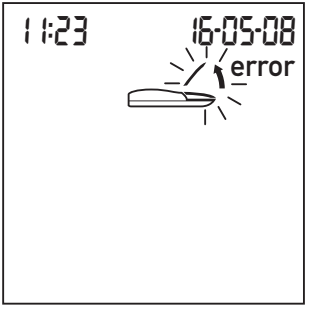
Solution

Remove the test strip. The error message disappears, the monitor is ready.

Turn the monitor off and allow it to stand for about 30 minutes at room temperature (+18°C to +32°C).

Display	Description of error
	**Error: battery** Battery level too low

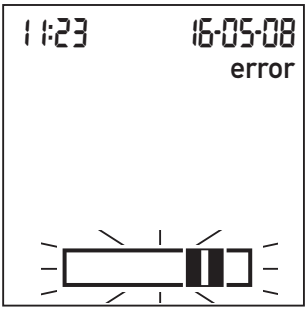
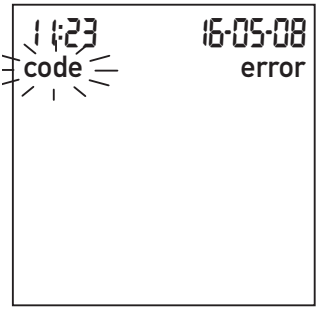
Error messages when preparing to test

	**Error: cover** The measurement chamber cover is not properly closed.

Solution

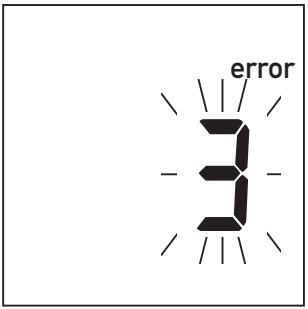
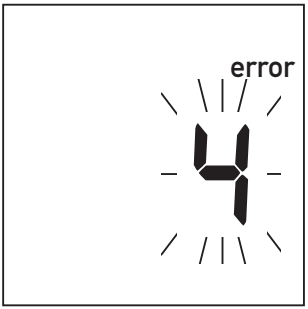
Insert new batteries as described on page 20.

Close the measurement chamber cover. The error message disappears, the monitor is ready.

Display	Description of error
	**Error: test strip** The test strip is unusable or the test strip is not a CoaguChek XS PT test strip.
	**Error: code chip** The code chip is missing, not properly inserted in the monitor, or damaged.

Solution
Remove the test strip and repeat the test with a new or correct test strip.
Insert the code chip, or remove it and re-insert it.

Error messages after the code number was confirmed

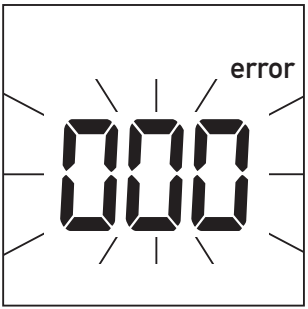
Display	Description of error
	**Error: test strip** The test strip is beyond its expiry date.
	**Error: test strip** The test strip is unusable.

Solution

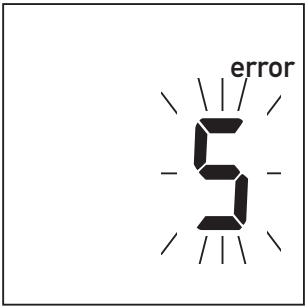
First check whether the date setting is correct in the monitor. If it is not, set the correct date.

If the date is correct: turn the monitor off, remove the code chip and test strip. Use a test strip from a new lot of test strips and insert the code chip that came with the new lot.

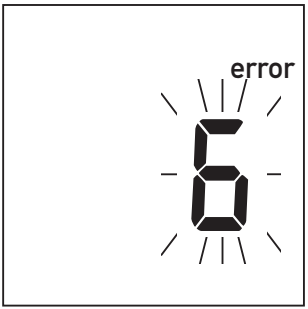
Turn the monitor off, remove the test strip and re-insert it. If the error message appears again, discard the unusable test strip and use a new one.

Display	Description of error
	**Error: time exceeded** The maximum allowed time of 120 seconds for applying blood has been exceeded.

Error messages during or after blood application

	**Error: blood application** Error applying blood to the test strip.

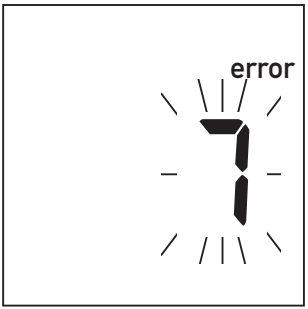
Solution
Turn the monitor off, remove the test strip and start a new test using the same test strip.
Turn the monitor off and remove the test strip. Re-read the instructions about applying blood (starting on page 43) and repeat the test with a new test strip.

Display	Description of error
	**Error: measurement** Measurement error
	Error: quality control The test strip failed the internal quality control check. The test strip is unusable.

Solution

Turn the monitor off and remove the test strip. Repeat the test with a new test strip. Do not touch or remove the test strip when a test is in progress.

Turn the monitor off and remove the test strip. Repeat the test with a new test strip. In case the error occurs again call Roche customer service.

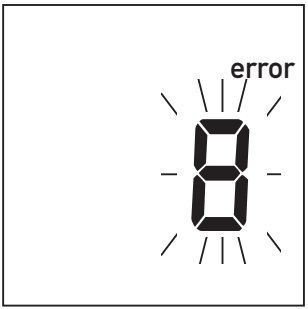
Display	Description of error
	**Error: measurement** Measurement error resulting from the blood sample.

Solution

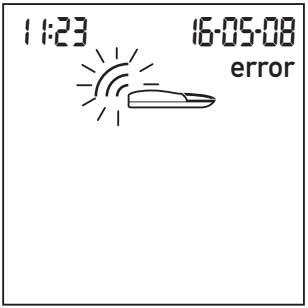
Turn the monitor off and remove the test strip. Repeat the measurement using a new test strip and blood taken from a new puncture site at the tip of another finger. Do not touch or remove the test strip when a test is in progress.

Note on Error 7 "Measurement": The CoaguChek XS PT test strip may be used for patients under a combination therapy of oral anticoagulants plus heparin injections. For maximum heparin concentrations which do not interfere with the test, please refer to the package insert. Under no circumstances, however, should heparinized capillary tubes be used for sample application. If capillaries are used, please use only the dedicated CoaguChek capillary tubes. Be sure to apply the blood drop to the test strip within 15 seconds of lancing the fingertip.

This error message (7) can occur in rare cases, i.e. in patients with long coagulation times (> 8 INR, < 5% Quick). If this error message appears again when you repeat the test, your results must be checked using another method. Please contact the doctor treating you immediately.

Display	Description of error
	**Error: diagnostic test** Error during the internal diagnostic test which the monitor performs.

Error message during infrared downloads

	**Error: infrared interface** Error during communication via the infrared interface caused by stray light.

Solution

Turn the monitor off and remove the batteries. Wait at least one minute before re-inserting the batteries in the battery compartment, and then set the date and time as described starting on page 26.

Repeat the test. If the error message persists, the monitor has a fault. Please call your local customer support and service centre (see page 100).

Data downloads are performed via the infrared interface and can be disturbed by bright surrounding light, especially if the light shines directly into the infrared window on the monitor or at the receiving end (e.g. on a computer).

Keep away from sources of stray light when downloading results.

Display information and symbols

These symbols may appear on the display. They have the meanings shown:

Symbol	Meaning
	Test strip (without sample application area)
	Test strip (with sample application area)
	Apply sample
	User must wait until the monitor has completed an action.
24 h	24-hour time format
12 h	12-hour time format
am	Time between midnight and noon (in 12-hour time format)
pm	Time between noon and midnight (in 12-hour time format)
%Q	Results are displayed as a Quick percentage value.
Sec	Results are displayed in seconds.
INR	Results are displayed in INR units.

Symbol	Meaning
On	Beep tone is turned on
OFF	Beep tone is turned off
 	Result is above the chosen therapeutic range (only with INR as unit) Result is below the chosen therapeutic range (only with INR as unit)
	• Results in the chosen unit • Error numbers
– – –	Memory contains no results or no further results
88:88	Time in the format hour : minutes.
88-88-88	Date in the format day-month-year, month-day-year, or year-month-day
set	The monitor is in Setup Mode.
code	Gives the code number of the code chip presently inserted.
>	Result in the chosen unit is above the measuring range.
<	Result in the chosen unit is below the measuring range.

Symbol	Meaning
	Battery status: • When the batteries still have their full charge, all segments are lit. • Individual segments disappear one by one as the batteries become weaker. • When there is no segment remaining, you can no longer perform a test. You can, however, still access the monitor's memory.
mem	The monitor is in Memory Mode.
	Automatic quality control completed successfully
C	Result for this blood test is flagged with a “c” due to a low haematocrit value or wet hands.
error	Reports an error (see Error messages)
	Room or monitor temperature is outside the acceptable range.
	Communication is taking place via the infrared interface
	Measurement chamber cover is open.

Further information

Ordering

Please contact your pharmacist or specialist supplier.

CoaguChek XS PT Test, 24 test strips	REF 0 4625358
CoaguChek XS PT Test, 2 x 24 test strips	REF 0 4625315
CoaguChek Softclix Lancet, 50 lancets	REF 0 3506509

Product limitations

Please read the information in the package insert supplied with the test strips for detailed product data and limitations.

Product specifications

Operating conditions and technical data

Temperature range	+18°C to +32°C
Relative humidity	10 to 85% (no condensation)
Maximum altitude	4300 m
Position	Place the monitor on a level, vibration-free surface or hold it so it is roughly horizontal.
Measuring range	%Q: 120 - 5 SEC: 9.6 - 96 INR: 0.8 - 8.0
Memory	100 test results with date and time
Interface	Infrared interface, LED/IRED Class 1
Battery operation	4 x 1.5 V batteries (alkali-manganese) type AAA
Number of tests per set of batteries	Up to 2 years or up to 300 tests (depending on frequency of use)
Safety class	III
Automatic power-off	After 3 minutes
Dimensions	138 x 78 x 28 mm
Weight	127 g (without batteries)

Sample material

Sample type	Capillary whole blood or non-anticoagulated, venous whole blood.
Sample size	At least 10 µL
Interactions	Refer to test strip package insert

Storage and transport conditions

Temperature range	-25°C to +70°C
Relative humidity	10 to 85% (no condensation)

Disposal of the CoaguChek XS monitor

During measurements the monitor itself may come into contact with blood. Used monitors therefore carry a risk of infection. Please dispose of your used monitor - after removing the batteries and cleaning the monitor - according to the regulations applicable in your country. For information about correct disposal please contact your local council.

The monitor falls outside the scope of the European Directive 2002/96/EC (Directive on waste electrical and electronic equipment (WEEE)).

For healthcare professionals:

Dispose of the monitor in line with your facility's procedures for dealing with potentially biohazardous waste.

Information service

If you have any further questions, please contact your local customer support and service centre.

United Kingdom
Roche Diagnostics Ltd.
Charles Avenue
Burgess Hill, RH15 9RY
CoaguChek Careline
0808 100 7666

Australia
Roche Diagnostics
Australia Pty Ltd.
31 Victoria Ave
Castle Hill NSW 2154
Telephone 02-98997999

Canada
Roche Diagnostics
201 Boulevard Armand-Frappier
Laval, Québec H7V 4A2
Coagulation Info-Line
Telephone 1-877-4-COAGUCHEK

New Zealand
Roche Diagnostics N.Z. Ltd.
15 Rakino Way
Mt. Wellington
Auckland
Telephone 09-2764157

Repairs

Please note that repairs and other modifications to the monitor may only be performed by persons authorized by Roche Diagnostics.

Guarantee

The statutory guarantee provisions on rights in consumer goods sales in the country of purchase shall apply.

The following U.S. Patents have been granted for the CoaguChek XS System (meter and test strips): 6,662,439; 7,073,246; 6,645,368; 6,881,378; 6,207,000; 7,049,131; 7,084,251; 5,625,036; 7,338,639. Additional U.S. Patents pending.

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Alphabetical index

A

Altitude (operating conditions) 11
Applying blood 54

B

Batteries
- inserting 20–22
- types 18, 20

Beep tone 52
- setting 37

Blood sample (testing) 43–63

C

Capillary blood sample (testing) 43–63
Cleaning 71–74
- by healthcare professionals 74
- test strip guide 72

Coagulation process 55
Coagulation units 36, 57, 60
Code chip 23–25, 51
- code number 24, 51
- inserting 24

Collecting blood 46

D
Date 32
Date format 31
Display
function check 21, 48
symbols 94–96
Disposal 18, 20, 24, 25, 58, 99

E
Electromagnetic interference 11
Error messages 75–93

F
Fingertip 53

G
Guarantee 101

H
Humidity 11

I
Information service 100
Infrared interface 67, 92

L
Lancing (your finger) 53

M

M button 29, 65
Measurement chamber cover 72
Measuring range 61
Memory 65–70
    erasing 68–70
Monitor
    setup 26–41
Monitor guide 17

O

Operating conditions 11, 98
Ordering 97

P

Prothrombin time 9

Q

Quality control 56

R

Result 57
    selecting the coagulation unit 36

S

Set button 28
Setup 26–41
- beep tone 37
- date 32
- date format 31
- setting up the monitor 28
- summary 27
- therapeutic range 38–39
- time 35
- time format 34
- unit 36

Starting up 19–25
Stray light 67, 92
Symbols
- blood drop 52
- clr 69
- error 75–93
- hourglass 52, 57, 70
- mem 65
- on packaging 2
- summary 94–96
- type plate 2

T

Target range 38, 59
setting 38–39
Technical data 98
Telephone number (information service) 100
Temperature range 11, 44
Test
performing 48–58
preparing 47
principle 10
Test strip
inserting 50
symbol 49
Therapeutic target range 38, 59
setting 38–39
Time 35
Time format 34

U

Unit
changing temporarily 60, 67
results (INR, %Quick, seconds) 36, 57, 60